SEP 1 8 2006

SECTION 6 - SUMMARY OF SAFETY AND EFFECTIVENESS

K062578
(Premarket Notification [510(k)] Number)

1. Applicant

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Corresponding Official:

Name: Ahava M. Stein, Consultant
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2. Device Name:	Digi-Lite TCD Device
Device trade/proprietary name:	Digi-Lite TCD Device
Common Name:	TransCranial Doppler (TCD) Device
Classification Name:	Ultrasonic Pulsed Doppler Imaging System (product code IYN, class II, classification section 892.1550). The device' transducers fall under classification section 892.1570; Diagnostic Ultrasonic Transducer, and product code ITX.

3. Predicate Devices

The Digi-Lite TCD device is substantially equivalent to the following device:

Device	Manufacturer	510(k) No.
Intra-View device	Rimed Ltd.	K974588

4. Intended Use

The Digi-Lite TCD device is intended for use in the non-invasive evaluation of intracranial and extracranial vascular flow velocity irregularities in adults and in children. It is not intended for fetal use. It is not intended for neonatal use.

5. Description of the Device

The Rimed Transcranial Doppler Systems are based on a PC platform system running under Microsoft Windows XP embedded. The product includes a Pentium M or equivalent processor, minimum 60 Gbyte hard disk, USB, RS232, LAN 10/100 RJ-45 network connection, a PC keyboard, mouse, touch screen of 15" TFT color SVGA that provides 1024 x 768 points graphic resolution.

In addition to the main PC card, the system hardware contains one Doppler Card that transmits the ultrasound power, translates the received signals to Doppler shift frequencies, and provides the required signal processing functionality. This card contains analog and digital circuits, a FPGA chip for timing and basic hardware digital signal processing, and a DSP chip for performing general control and digital signal processing algorithms.

The complete system contains one Doppler card, two 2 MHz probes, a 1MHz probe, a 4 MHz probe, and an 8 MHz probe. In addition, a Remote Control unit, printer and Foot Switch can be used.

6. Technological Characteristics Compared to Predicate Device

The technological characteristics, e.g., overall design, materials, mechanism of action, mode of operation, performance characteristics, etc., and the intended use of the Digi-Lite TCD device are substantially equivalent to the predicate device cited above.

7. Performance Testing

The following performance testing activities were performed for the Digi-Lite™ device:

A. Software Validation

B. Electromagnetic Compatibility/ Electrical Safety Testing

C. Performance Testing- Bench- according to the FDA guidance for ultrasound devices (September 1997), the following tests were performed:

   a. Acoustic output testing

   b. Clinical measurement accuracy

   c. Doppler sensitivity testing

   d. Estimate of temperature rise

Testing results for all validation tests, demonstrated that the Digi-Lite™ device performs according to its specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 18 2006

Rimed Ltd.
% Ms. Ahava Stein
A. Stein Regulatory Consulting
20 Hata'as St.
Kfar Saba, 44425
ISRAEL

Re: K062578
Trade Name: Digi-Lite TCD Device
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: IYN and ITX
Dated: August 23, 2006
Received: August 31, 2006

Dear Ms. Stein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Digi-Lite TCD Device, as described in your premarket notification:

Transducer Model Number

1 MHz PW
2 MHz PW
4 MHz PW
8MHz

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Andrew Kang at (301) 594-1212.

Sincerely yours,

Carolyn Y Neuland

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use Statement

510(k) Number (if known): K062578

Device Name: Digi-Lite TCD device

Indications for use: The Digi-Lite Trans Cranial and Vascular Doppler (TCD) is intended for use in the non-invasive evaluation of intracranial and extracranial vascular flow velocity irregularities in adults and in children. It is not intended for fetal use. It is not intended for neonatal use.

Prescription Use √ (Per 21 C.F.R. 801.109) OR Over-The-Counter Use___ (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carolyn Y Neuland for N Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062578

K062578

Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Digi-Lite System:

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	C	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic				X	X					
Fetal										
Abdominal										
Intra-operative (Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic				X						
Cardiac										
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular				X	X					
Laparoscopic										
Musculo-Skeletal Conventional										
Muscolo-Skeletal Superficial										
Other (Specify)										

Additional Comments:

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Carolyn Y Neuland for N.C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062578

K062578

Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

1 MHZ PW HAND-HELD TRANSDUCER

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	C	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic				X						
Fetal										
Abdominal										
Intra-operative (Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic				X						
Cardiac										
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular				X						
Laparoscopic										
Musculo-Skeletal Conventional										
Muscolo-Skeletal Superficial										
Other (Specify)										

Additional Comments:

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Prescription Use (Per 21 CFR 801.109)

Carolyn Neuland for N.C. Brogdon

(Division Sign-Off)

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510(k) Number K062578

K062578

Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

2 MHZ PW HAND-HELD TRANSDUCER

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	C	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic				X						
Fetal										
Abdominal										
Intra-operative (Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic				X						
Cardiac										
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular				X						
Laparoscopic										
Musculo-Skeletal Conventional										
Muscolo-Skeletal Superficial										
Other (Specify)										

Additional Comments:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Carolyn Y Neuland for N C Brogdon

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K062578

K062578

Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

4 MHZ TRANSDUCER

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	C	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic				X	X					
Fetal										
Abdominal										
Intra-operative (Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular				X	X					
Laparoscopic										
Musculo-Skeletal Conventional										
Muscolo-Skeletal Superficial										
Other (Specify)										

Additional Comments:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K062578

K062578

Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

8 MHZ TRANSDUCER

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	C	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic				X	X					
Fetal										
Abdominal										
Intra-operative (Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular				X	X					
Laparoscopic										
Musculo-Skeletal Conventional										
Muscolo-Skeletal Superficial										
Other (Specify)										

Additional Comments:

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...ical Devices K062578